

THE CLAIMS

1. (CURRENTLY AMENDED) A method of increasing the bioavailability of azithromycin, comprising co-administering, to a mammal in need of such treatment, a combination of azithromycin and ~~pluronic L64~~ poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol) having approximately 10% ethylene oxide by weight and having an average molecular weight of the propylene oxide block of approximately 1800.
2. (CURRENTLY AMENDED) A method as defined in claim 1, wherein said azithromycin and said ~~pluronic L64~~ poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol) having approximately 10% ethylene oxide by weight and having an average molecular weight of propylene oxide block of approximately 1800 are each administered in an amount such that the combination is antimicrobially effective.
3. (ORIGINAL) A method as defined in claim 1, wherein said bioavailability increase is measured in blood serum.
4. (CURRENTLY AMENDED) A method as defined in claim 1, wherein said ~~pluronic L64~~ poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol) having approximately 10% ethylene oxide by weight and having an average molecular weight of propylene oxide block of approximately 1800 and azithromycin are co-administered separately.
5. (CURRENTLY AMENDED) A method as defined in claim 4, wherein said ~~pluronic L64~~ poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol) having approximately 10% ethylene oxide by weight and having an average molecular weight of propylene oxide block of approximately 1800 and azithromycin are co-administered by different routes.
6. (CURRENTLY AMENDED) A method as defined in claim 5, wherein said ~~pluronic L64~~ poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol) having

approximately 10% ethylene oxide by weight and having an average molecular weight of propylene oxide block of approximately 1800 is administered orally and said azithromycin is administered intravenously.

7. (CURRENTLY AMENDED) A method as defined in claim 4, wherein said azithromycin and said ~~pluronic L61~~ poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol) having approximately 10% ethylene oxide by weight and having an average molecular weight of propylene oxide block of approximately 1800 are both administered orally.

8. (CURRENTLY AMENDED) A method as defined in claim 1, wherein said ~~pluronic L61~~ poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol) having approximately 10% ethylene oxide by weight and having an average molecular weight of propylene oxide block of approximately 1800 and azithromycin are co-administered together in a composition.

9. (CURRENTLY AMENDED) A method as defined in claim 1, wherein said ~~pluronic L61~~ poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol) having approximately 10% ethylene oxide by weight and having an average molecular weight of propylene oxide block of approximately 1800 is co-administered in an amount such that the oral bioavailability of azithromycin is increased by at least 25%.

10. (CURRENTLY AMENDED) A method as defined in claim 9, wherein said ~~pluronic L61~~ poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol) having approximately 10% ethylene oxide by weight and having an average molecular weight of propylene oxide block of approximately 1800 is co-administered in an amount such that the oral bioavailability of azithromycin is increased by at least 50%.

11. (CURRENTLY AMENDED) A method as defined in claim 10, wherein said ~~pluronic L61~~ poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol) having

approximately 10% ethylene oxide by weight and having an average molecular weight of propylene oxide block of approximately 1800 is co-administered in an amount such that the oral bioavailability of azithromycin is increased by at least 75%.

12. (CURRENTLY AMENDED) A method as defined in claim 1, wherein said increase is measured as an increase in AUC relative to dosing in the absence of ~~pluronic L61~~ poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol) having approximately 10% ethylene oxide by weight and having an average molecular weight of propylene oxide block of approximately 1800.

13-17. (CANCELED).

18. (CURRENTLY AMENDED) A method of increasing the C<sub>max</sub> of azithromycin, comprising co-administering, to a mammal in need of such treatment, a combination of azithromycin and ~~pluronic L61~~ poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol) having approximately 10% ethylene oxide by weight and having an average molecular weight of propylene oxide block of approximately 1800.

19. (CURRENTLY AMENDED) A method as defined in claim 18, wherein said azithromycin and ~~pluronic L61~~ poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol) having approximately 10% ethylene oxide by weight and having an average molecular weight of propylene oxide block of approximately 1800 are each administered in an amount such that the combination is antimicrobially effective.

20. (ORIGINAL) A method as defined in claim 18, wherein said C<sub>max</sub> increase is measured in blood serum.

21. (CURRENTLY AMENDED) A method as defined in claim 18, wherein said ~~pluronic L61~~ poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol) having

approximately 10% ethylene oxide by weight and having an average molecular weight of propylene oxide block of approximately 1800 and azithromycin are co-administered separately.

22. (CURRENTLY AMENDED) A method as defined in claim 21, wherein said ~~pluronic~~ L64 poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol) having approximately 10% ethylene oxide by weight and having an average molecular weight of propylene oxide block of approximately 1800 and azithromycin are co-administered by different routes.

23. (CURRENTLY AMENDED) A method as defined in claim 22, wherein said ~~pluronic~~ L64 poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol) having approximately 10% ethylene oxide by weight and having an average molecular weight of propylene oxide block of approximately 1800 is administered orally and said azithromycin is administered intravenously.

24. (CURRENTLY AMENDED) A method as defined in claim 21, wherein said azithromycin and said ~~pluronic~~ L64 poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol) having approximately 10% ethylene oxide by weight and having an average molecular weight of propylene oxide block of approximately 1800 are both administered orally.

25. (CURRENTLY AMENDED) A method as defined in claim 18, wherein said ~~pluronic~~ L64 poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol) having approximately 10% ethylene oxide by weight and having an average molecular weight of propylene oxide block of approximately 1800 and azithromycin are co-administered together in a composition.

26. (CURRENTLY AMENDED) A method as defined in claim 18, wherein said ~~pluronic~~ L64 poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol) having approximately 10% ethylene oxide by weight and having an average molecular weight of

propylene oxide block of approximately 1800 is co-administered in an amount such that the Cmax of azithromycin is increased by at least 25%.

27. (CURRENTLY AMENDED) A method as defined in claim 26, wherein said ~~pluronic L64~~ poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol) having approximately 10% ethylene oxide by weight and having an average molecular weight of propylene oxide block of approximately 1800 is co-administered in an amount such that the Cmax of azithromycin is increased by at least 50%.

28. (CURRENTLY AMENDED) A method as defined in claim 27, wherein said ~~pluronic L64~~ poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol) having approximately 10% ethylene oxide by weight and having an average molecular weight of propylene oxide block of approximately 1800 is co-administered in an amount such that the Cmax of azithromycin is increased by at least 75%.

29-33. (CANCELED).

34. (CURRENTLY AMENDED) A method of increasing the concentration of azithromycin in a cell or a tissue, comprising co-administering, to a mammal in need of such treatment, a combination of azithromycin and ~~pluronic L64~~ poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol) having approximately 10% ethylene oxide by weight and having an average molecular weight of propylene oxide block of approximately 1800.

35. (CURRENTLY AMENDED) A method as defined in claim 34, wherein said azithromycin and said ~~pluronic L64~~ poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol) having approximately 10% ethylene oxide by weight and having an average molecular weight of propylene oxide block of approximately 1800 are each administered in an amount such that the combination is antimicrobially effective.

36. (CURRENTLY AMENDED) A method as defined in claim 34, wherein said ~~pluronic L64~~ poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol) having approximately 10% ethylene oxide by weight and having an average molecular weight of propylene oxide block of approximately 1800 and azithromycin are co-administered separately.

37. (CURRENTLY AMENDED) A method as defined in claim 36, wherein said ~~pluronic L64~~ poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol) having approximately 10% ethylene oxide by weight and having an average molecular weight of propylene oxide block of approximately 1800 and azithromycin are co-administered by different routes.

38. (CURRENTLY AMENDED) A method as defined in claim 37, wherein said ~~pluronic L64~~ poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol) having approximately 10% ethylene oxide by weight and having an average molecular weight of propylene oxide block of approximately 1800 is administered orally and said azithromycin is administered intravenously.

39. (CURRENTLY AMENDED) A method as defined in claim 34, wherein said azithromycin and said ~~pluronic L64~~ poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol) having approximately 10% ethylene oxide by weight and having an average molecular weight of propylene oxide block of approximately 1800 are both administered orally.

40. (CURRENTLY AMENDED) A method as defined in claim 34, wherein said ~~pluronic L64~~ poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol) having approximately 10% ethylene oxide by weight and having an average molecular weight of propylene oxide block of approximately 1800 and azithromycin are co-administered together in a composition.

41. (CURRENTLY AMENDED) A method as defined in claim 34, wherein said ~~pluronic L64~~

poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol) having approximately 10% ethylene oxide by weight and having an average molecular weight of propylene oxide block of approximately 1800 is co-administered in an amount such that said concentration of azithromycin is increased by at least 25%.

42. (CURRENTLY AMENDED) A method as defined in claim 41, wherein said ~~pluronic-L64~~ poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol) having approximately 10% ethylene oxide by weight and having an average molecular weight of propylene oxide block of approximately 1800 is co-administered in an amount such that said concentration of azithromycin is increased by at least 50%.

43. (CURRENTLY AMENDED) A method as defined in claim 42, wherein said ~~pluronic-L64~~ poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol) having approximately 10% ethylene oxide by weight and having an average molecular weight of propylene oxide block of approximately 1800 is co-administered in an amount such that said concentration of azithromycin is increased by at least 75%.

44-48. (CANCELED).

49. (CURRENTLY AMENDED) A composition comprising azithromycin and ~~pluronic-L64~~ poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol) having approximately 10% ethylene oxide by weight and having an average molecular weight of propylene oxide block of approximately 1800, said ~~pluronic-L64~~ poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol) having approximately 10% ethylene oxide by weight and having an average molecular weight of propylene oxide block of approximately 1800 being present in an amount such that, following administration, the azithromycin has an oral bioavailability greater than 37%.

50. (CURRENTLY AMENDED) A composition as defined in claim 49, wherein said ~~pluronic~~

~~L61~~ poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol) having approximately 10% ethylene oxide by weight and having an average molecular weight of propylene oxide block of approximately 1800 is present in an amount such that said oral bioavailability of azithromycin is increased by at least 25%.

51. (CURRENTLY AMENDED) A composition as defined in claim 50, wherein said ~~pluronic~~ L61 poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol) having approximately 10% ethylene oxide by weight and having an average molecular weight of propylene oxide block of approximately 1800 is co-administered in an amount such that the oral bioavailability of azithromycin is increased by at least 50%.

52. (CURRENTLY AMENDED) A composition as defined in claim 51, wherein said ~~pluronic~~ L61 poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol) having approximately 10% ethylene oxide by weight and having an average molecular weight of propylene oxide block of approximately 1800 is co-administered in an amount such that the oral bioavailability of azithromycin is increased by at least 75%.

53-56. (CANCELED).

57. (CURRENTLY AMENDED) A composition which increases the C<sub>max</sub> of azithromycin, comprising azithromycin and ~~pluronic~~ L61 poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol) having approximately 10% ethylene oxide by weight and having an average molecular weight of propylene oxide block of approximately 1800.

58. (CURRENTLY AMENDED) A composition as defined in claim 57, wherein said ~~pluronic~~ L61 poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol) having approximately 10% ethylene oxide by weight and having an average molecular weight of propylene oxide block of approximately 1800 is present in an amount such that said C<sub>max</sub> is increased by at least 25%.



59. (CURRENTLY AMENDED) A composition as defined in claim 58, wherein said ~~pluronic~~ L64 poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol) having approximately 10% ethylene oxide by weight and having an average molecular weight of propylene oxide block of approximately 1800 is co-administered in an amount such that the Cmax of azithromycin is increased by at least 50%.

60. (CURRENTLY AMENDED) A composition as defined in claim 59, wherein said ~~pluronic~~ L64 poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol) having approximately 10% ethylene oxide by weight and having an average molecular weight of propylene oxide block of approximately 1800 is co-administered in an amount such that the Cmax of azithromycin is increased by at least 75%.

61-64. (CANCELED).

65. (CURRENTLY AMENDED) A composition which increases the concentration of azithromycin in a cell or a tissue, comprising azithromycin and ~~pluronic~~ L64 poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol) having approximately 10% ethylene oxide by weight and having an average molecular weight of propylene oxide block of approximately 1800.

66. (CURRENTLY AMENDED) A composition as defined in claim 65, wherein said ~~pluronic~~ L64 poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol) having approximately 10% ethylene oxide by weight and having an average molecular weight of propylene oxide block of approximately 1800 is present in an amount such that said increase is at least 25%.

67. (CURRENTLY AMENDED) A composition as defined in claim 66, wherein said ~~pluronic~~ L64 poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol) having

approximately 10% ethylene oxide by weight and having an average molecular weight of propylene oxide block of approximately 1800 is co-administered in an amount such that said increase is at least 50%.

68. (CURRENTLY AMENDED) A composition as defined in claim 67, wherein said ~~pluronic~~ L61 poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol) having approximately 10% ethylene oxide by weight and having an average molecular weight of propylene oxide block of approximately 1800 is co-administered in an amount such that said increase is at least 75%.

69-72. (CANCELED).

73. (CURRENTLY AMENDED) A kit comprising:

(1) a therapeutically effective amount of a composition comprising azithromycin, plus a pharmaceutically acceptable carrier or diluent, in a first dosage form;

(2) a therapeutically effective amount of a composition comprising a compound which is pluronic L61 poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol) having approximately 10% ethylene oxide by weight and having an average molecular weight of propylene oxide block of approximately 1800, plus a pharmaceutically acceptable carrier or diluent, in a second dosage form; and

(3) a container for containing said first and second dosage forms.

74. (ORIGINAL) A kit as defined in claim 73, adapted for administration to a human.

75. (ORIGINAL) A kit as defined in claim 73, further comprising directions for the administration of said compositions.